K094009

Halt MEDICAL

JUN 14 2010

510(K) SUMMARY

As Required By 21 CFR 807.92

Page 1 of (3)

Date of Summary Preparation	June 7, 2010
Submitter and Owner's Name and Address	Halt Medical, Inc. 131 Sand Creek Road, Suite B Brentwood, CA 94513 Main: (925) 634-7943 Fax: (925) 634-7841
Contact Person	Clarisa A. Tate Director of RA/QA, Halt Medical, Inc. Office: (925) 271-0626 e-mail: ctate@haltmedical.com
Trade Name	Halt 2000GI™ Electrosurgical Radiofrequency Ablation System
Common/Classification Name	Electrosurgical, cutting and coagulation device and accessories
Classification	Class II
Product Code	GEI
Classification Panel	General and Plastic Surgery
Classification Regulation	21 CFR §878.4400
Legally Marketed Device to which substantial equivalence is claimed	Rita Medical Systems - Electrosurgical RF Generator and accessories: • Rita Model 1500 (K993944) • Rita Model 1500X (K032149)
Intended Use	The Halt 2000GI™ Electrosurgical Radiofrequency Ablation System is indicated for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of soft tissue.
Device Description	The Halt 2000GI™ Electrosurgical Radiofrequency Ablation System includes the following system components: • Halt 2000GI Radiofrequency Generator (RF Generator): that provides RF energy to the RF Probe

- Disposable RF Probe (Tulip™, TU 1000), a hand piece with a trocar-pointed shaft and 7 deployable RF needle electrodes.
- RF Probe Extension Cable that connects the RF Probe to the RF Generator.
- Dispersive Electrode Pads (TSP 115) Set that provides the return path for the RF energy applied by the RF Probe. *(Use only Dispersive Electrode Pads provided by Halt Medical, Inc.)*
- Dispersive Electrode Pad Set Extension Cable (TSPCBL) that connects the Dispersive Electrode Pad Set to the RF Generator.
- Power Cord that is a medical grade power cord providing AC power to the RF Generator.
- Foot Pedal that is a pneumatic foot pedal with tubing used to turn RF energy on and off.

The Halt 2000GI™ Electrosurgical Radiofrequency Ablation System is designed to deliver up to 200 W of RF power at 460 kHz in three operational modes: Temperature Control, Manual Control and Coagulation Mode. A touch screen with a graphical user interface (GUI) enables selection of operational parameters such as the mode of operation, the ablation time, the target temperature, and the power delivery level. With the RF probe placed in the tissue to be ablated and its electrodes deployed, RF power can be turned on. The system parameters are continuously monitored and displayed on the RF Generator. If the measured parameters are outside the acceptable limits, the RF energy delivery automatically stops and a message appears on the graphical user interface. RF energy during an ablation or coagulation can also be stopped at any time by the user by pressing the foot pedal.

Technological Characteristics Compared to Predicate Devices

The design features and principal modes of operation of the Halt 2000GI™ System is equivalent to commercially available RF Ablation Systems specifically the predicate devices listed above.

Substantial equivalence is established with respect to similar intended use, principal design, type of energy used or delivered, materials, performance and safety requirements.

The key similarities and differences of the Halt RFA System to the legally marketed RITA RF Ablation Systems are summarized below:

- Both Utilizes RF energy at equivalent frequencies (approximately 450 kHz), sinusoidal waveforms and

	equivalent power levels (150 – 250 Watts) • Both incorporates the same surgical and technical concepts for the in situ delivery and control of RF energy through deployable array needle electrodes with impedance and temperature feedback under visual control. • Halt RF Probe (Tulip) features seven deployable needle electrodes, a live trocar tip, and provides real-time simultaneous feedback from all seven temperature sensors while RITA® Probe features nine deployable needle electrodes, a hollow shaft with a needle tip, and provides real-time temperature feedback from five independent temperature sensors within the array. • Halt RF Probe (Tulip) is designed to create single ablations up to 6 cm in size while RITA Probe is up to 5 cm. Both can also be used to ablate the needle track. • Both the RF Probes use similar medical grade metal alloys and plastic polymers (i.e. Nitinol®, surgical grade Stainless Steel and PEEK).
Performance Testing	The Halt 2000GI™ Electrosurgical Radiofrequency Ablation System was subjected to a battery of electrical, mechanical, and software validation testing, as well as applicable safety requirements (EN/IEC 60601-1, EN/IEC 60601-1-2, EN/IEC 60601-2-2, ANSI/AAMI HF-18). The system passed all testing. Animal and bench testing also successfully demonstrates that the Halt RF Ablation System performs as intended and per specifications. The ablation capability was confirmed and the radiofrequency ablation provides a reproducible, discretely demarcated zone of tissue necrosis which was surrounded by normal tissue perfused with blood. A series of biocompatibility testing also demonstrated that the device materials are safe, suitable, and appropriate for their intended use and in compliance with ISO 10993-1, ISO 10993-5, and ISO 10993-10.
Conclusion	The Halt 2000GI™ Electrosurgical Radiofrequency Ablation System with its indication for use, is substantially equivalent to the legally marketed medical device as demonstrated by the technological characteristics comparison and performance testing completed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Halt Medical, Inc.
% Mr. Russ DeLonzor
President & COO
131 Sand Creek Road, Suite B
Brentwood, California 94513

JUN 14 2010

Re: K094009
Trade/Device Name: Halt 2000GI Electrosurgical Radiofrequency Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 13, 2010
Received: April 15, 2010

Dear Mr. DeLonzor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K094009

Device Name: Halt 2000GI™ Electrosurgical Radiofrequency Ablation System

Indications for Use:

The Halt 2000GI™ Electrosurgical Radiofrequency Ablation System is indicated for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of soft tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K094009

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____